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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/817,781	03/26/2001	Paul C. Harris	2065.2001-000	7810

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EXAMINER

NGUYEN, BAO THUY L

ART UNIT PAPER NUMBER

1641

DATE MAILED: 09/26/2002

8

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/817,781

Applicant(s)

HARRIS ET AL.

Examiner

Bao-Thuy L. Nguyen

Art Unit

1641

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 August 2002.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-32 is/are pending in the application.
- 4a) Of the above claim(s) 16-32 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4 & 6.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION***Election/Restrictions***

1. Applicant's election with traverse of Group I, claims 1-15, in Paper No. 8 is acknowledged. The traversal is on the ground(s) that a single art search is all that is required to identify the relevant art for Groups I, II and III, thus there is no additional search burden in combining Groups I, II and III. Applicant also argues that Groups I and II are both sandwich methods for detecting an analyte, even though the fluid sample is applied at a different point on the solid phase in the methods of Group I and Group II, the determination of the corrected analyte-binding particle amount for both methods uses the same principle. These arguments have been fully considered but are not found persuasive. Each of the Group is directed to a method for conducting an assay. Each method requires separate and distinct method steps and the assay principle is different, i.e competitive vs sandwich, therefore, a search for Group I does not necessarily encompass a search for Groups II and III. Furthermore, the different application point in Groups I and II, requires two separate searches in order to locate prior art for such a method step, i.e. a search for one application point does not encompass a search for another application point. The argument that the determination step is the same in all groups is not persuasive since the claims comprises more than just an analysis step that may be similar.

As clearly demonstrated in the election/restriction requirement, each of the group are distinct and have acquired a separate status in the art as shown by their different classification, the search and examination require for Group I is not required for Groups II and III and would pose a serious burden on the Office, restriction for examination purposes as indicated is proper and is therefore made FINAL.

Claim Rejections - 35 USC § 112

2. Claims 1-15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-15 are vague and indefinite with respect to the recitation of the analyte-binding particles in part c) of claim 1. These particles are recited as being immobilized in the contact region. However, part d) of claim 1 requires that these particles migrate by capillary action through the sample capture zone, the control capture zone and beyond, into a wicking pad. If these particles are immobilized, how do they move out of the contact region and beyond?

Part e) of claim 1 is also confusing with respect to the recitation of the binding relationship between the control capture reagent and the analyte-binding particles. What exactly does the control capture reagent bind to? The analyte that is bound by the analyte-binding agent on the particles? Or the analyte-binding agent itself? Or the particles? Does the control capture reagent bind to the analyte-binding particle irrespective of the presence or absence of analyte? In other words, does it bind excess analyte-binding particle, i.e. those that do not have analyte bound to them?

The recitation of "determining a corrected analyte-binding particle amount" is indefinite because it is unclear how, exactly, has the amount been "corrected".

Claim 6 is confusing because it is unclear how the particles are "labeled". From claim 1, it appears that the particles are the label, thus, it is unclear how the label is further labeled?

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

4. The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

5. Claims 1-15 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Kuo et al (US 6,436,721 B1).

Kuo discloses a method and device for determination of an analyte in a sample of body fluid. The test strip comprises a matrix made of paper, nitrocellulose or nylon material (column 3, lines 58-50). The strip has a first region which contains mobile specific binding partner for the analyte which bears a detectable label such as gold sol or latex particles (column 2, lines 29-33; and column 5, lines 57-58); a second region containing immobilized binding partner which is specific for an epitope of the analyte different than that to which analyte binding gold sol particles are specific; and a third region containing means for capturing the analyte/labeled specific binding partner complex which is not bound in the second region (column 2, lines 33-39). The third region may also contains an immobilized antibody against the labeled binding

Art Unit: 1641

partner (e.g. anti-mouse IgG when the labeled binding partner is an antibody). See column 4, lines 24-28. Kuo also teaches an absorbent pad which serves to absorb the liquid that migrates pass the various zones of the test strip (column 9, lines 47-50). In use, sample is applied to the test strip at an application point, (area 1 of figure 1) and allows to migrate to the various zones of the test strip. Signals from the detectable label in the second region (sample capture zone) and from the detectable label in the third region (control capture zone) are measured and the ratios of these signals is determined and related to the amount of the analyte in the sample. Kuo teaches that such a determination provides the advantage of an increase in accuracies because it corrects for inaccuracies in labeled conjugate deposition and/or non-uniform flow through the matrix (column 4, lines 21-39). Kuo also teaches a method in which the summation of the signal from both the sample capture and control capture zones is taken, and the ratio of the signal in the sample capture zone and the sum is used to determine the amount of analyte (column 5, lines 2-40). Kuo teaches that the test strip and method disclosed may be adapted to determine various types of analytes such as PSA and hCG (column 8, lines 34-50) in body samples such as serum.

Conclusion

6. No claim is allowed.

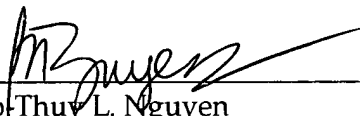
7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bao-Thuy L. Nguyen whose telephone number is (703) 308-4243. The examiner can normally be reached on Monday, Wednesday and Thursday from 9:00 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on (703) 305-3399. The fax phone numbers for the

Art Unit: 1641

organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.



Bao-Thuy L. Nguyen
Primary Examiner
Art Unit 1641
September 24, 2002